IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CEPHALON FRANCE, Plaintiffs and Counterclaim-Defendants, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., MATRIX LABORATORIES LIMITED, and MATRIX LABORATORIES, INC., Defendants and Counterclaim-Plaintiffs.	)	C.A. No. 09-954-GMS

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANT MYLAN PHARMACEUTICALS INC.

Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals"), by and through the undersigned attorneys, answers the Complaint for Patent Infringement ("Complaint") of Cephalon, Inc. and Cephalon France (collectively, "Cephalon") as follows:

PARTIES

1. Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon, Inc. is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

ANSWER: Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 1 and, therefore, denies them.

2. Cephalon France is a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

ANSWER: Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2 and, therefore, denies them.

3. On information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

ANSWER: Admitted.

4. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

ANSWER: Admitted.

5. On information and belief, Matrix Laboratories Limited ("Matrix Ltd.") is a corporation organized and existing under the laws of India, with a principal place of business at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad – 500 003, India.

ANSWER: Admitted.

6. On information and belief, Matrix Laboratories Inc. ("Matrix Inc.") is a corporation organized and existing under the laws of Delaware, with a principal place of business at 76 South Orange Avenue, Suite 301, South Orange, New Jersey 07079.

ANSWER: Admitted.

7. On information and belief, Mylan Inc. is the parent corporation of Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc.

ANSWER: Admitted that Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. The remaining allegations in paragraph 7 are denied.

8. On information and belief, Mylan Pharmaceuticals, itself and through Mylan Inc., Matrix Ltd., and Matrix Inc., is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

ANSWER: Admitted that Mylan Pharmaceuticals is in the business of manufacturing and selling generic pharmaceutical products, which are distributed, marketed and/or sold in the United States. The remaining allegations in paragraph 8 are denied.

9. On information and belief, Mylan Inc., itself and through its wholly-owned subsidiaries, Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc., is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

ANSWER: Admitted that Mylan Pharmaceuticals is in the business of manufacturing and selling generic pharmaceutical products, which are distributed, marketed and/or sold in the United States. The remaining allegations in paragraph 9 are denied.

JURISDICTION AND VENUE

10. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Admitted that this action for alleged patent infringement purports to arise under the Patent Laws of the United States of America. Admitted that subject matter jurisdiction exists over Mylan Pharmaceuticals pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue over Mylan Pharmaceuticals in this judicial district is not proper, but will not be contested for the limited purposes of this action only. Cephalon has stipulated to the dismissal of Mylan Inc., Matrix Ltd., and Matrix Inc. from this action, and accordingly, Mylan Pharmaceuticals does not respond to paragraph 10 as it relates to Mylan Inc., Matrix Ltd., and Matrix Inc.

11. This Court has personal jurisdiction over Mylan Inc., Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc. by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

ANSWER: Denied, as the allegations in paragraph 11 state a legal conclusion for which no answer is required. To the extent an answer is deemed required, Mylan Pharmaceuticals does not contest personal jurisdiction for the limited purposes of this action only. Cephalon has stipulated to the dismissal of Mylan Inc., Matrix Ltd., and Matrix Inc. from this action, and accordingly, Mylan Pharmaceuticals does not respond to paragraph 10 as it relates to Mylan Inc., Matrix Ltd., and Matrix Inc.

NATURE OF THIS ACTION

12. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 20-0043 filed by Mylan with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Cephalon's successful Nuvigil® pharmaceutical products that are sold in the United States.

ANSWER: Mylan Pharmaceuticals admits that Cephalon purports to bring this action pursuant to the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e), and that this action is purportedly related to Abbreviated New Drug

Application ("ANDA") No. 20-0043 filed by Mylan Pharmaceuticals with the United States Food and Drug Administration ("FDA") for approval to market generic armodafinil products in the United States. Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 12 and, therefore, denies them.

BACKGROUND

13. Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths, as indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

ANSWER: Mylan Pharmaceuticals admits that Cephalon, Inc. is indicated in the records of the FDA as the holder of approved New Drug Application ("NDA") No. 21-875 for Nuvigil® tablets in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths. Mylan Pharmaceuticals further admits that Nuvigil® is listed in the FDA's Electronic Orange Book with respect to NDA No. 21-875 and that the Electronic Orange Book references active ingredient armodafinil with respect to Nuvigil®. Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 13 and, therefore, denies them.

14. Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Reissue Patent No. RE37,516 E ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size." The '516 patent was duly and legally issued by the United States Patent and Trademark Office on January 15, 2002. A true and correct copy of the '516 patent is attached as Exhibit A.

ANSWER: Mylan Pharmaceuticals admits that United States Reissue Patent No. RE37,516 E ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size," issued on January 15, 2002 and identifies Cephalon, Inc. as the assignee. Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 14 and, therefore, denies them.

15. Cephalon France is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,132,570 B2 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil."

The '570 patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 2006. A true and correct copy of the '570 patent is attached as Exhibit B.

ANSWER: Mylan Pharmaceuticals admits that United States Patent No. 7,132,570 B2 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil," issued on November 7, 2006 and identifies Cephalon France as the assignee. Mylan Pharmaceuticals lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 15 and, therefore, denies them.

16. Upon information and belief, Mylan filed ANDA No. 20-0043 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil capsules in 50 mg, 150 mg, and 250 mg dosage strengths, which was amended to provide for the additional dosage strengths of 100 mg and 200 mg ("Mylan's generic armodafinil products"), before the expiration of the '516 and '570 patents ("patents-in-suit"). On information and belief, as part of its ANDA, Mylan filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patents-in-suit are "invalid or will not be infringed by the manufacture, use, or sale of" Mylan's generic armodafinil products that are the subject of Mylan's ANDA No. 20-0043.

ANSWER: Admitted that Mylan Pharmaceuticals filed ANDA No. 20-0043 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil capsules in 50 mg, 150 mg, and 250 mg dosage strengths, which was amended to provide for the additional dosage strengths of 100 mg and 200 mg ("Mylan Pharmaceuticals' proposed generic armodafinil products"), before the expiration of the '516 and '570 patents ("the patents-in-suit"). Mylan Pharmaceuticals further admits that as part of its ANDA, Mylan Pharmaceuticals filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV), asserting that the patents-in-suit are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" Mylan Pharmaceuticals' proposed generic armodafinil products that are the subject of Mylan Pharmaceuticals' ANDA No. 20-0043. Mylan Pharmaceuticals further admits that its Paragraph IV Certification also asserted that U.S. Patent No. 7,297,346 B2 ("the '346 Patent"), entitled "Pharmaceutical Formulations of Modafinil," which issued on November 20, 2007 and identifies Cephalon Inc. as the assignee is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale

of" Mylan Pharmaceuticals' proposed generic armodafinil products that are the subject of Mylan Pharmaceuticals' ANDA No. 20-0043. Any other allegations, including all allegations against Mylan Inc., Matrix Ltd., and Matrix Inc., in paragraph 16 are denied.

17. Mylan caused to be sent to Cephalon a letter ("the Notice Letter"), dated November 2, 2009, notifying Cephalon that Mylan had filed ANDA No. 20-0043 seeking approval to market Mylan's generic armodafinil products prior to the expiration of the patents-in-suit, and was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon received the Notice Letter on or about November 3, 2009.

ANSWER: Admitted that on November 2, 2009, Mylan Pharmaceuticals (through its outside counsel) sent Cephalon a Notice of Paragraph IV Certification as to the patents-in-suit and the '346 patent in accordance with 21 U.S.C. § 355(j)(2)(B)(iv), the delivery of which was accepted by Cephalon on November 3, 2009. Any other allegations, including all allegations against Mylan Inc., Matrix Ltd., and Matrix Inc., in paragraph 17 are denied.

18. The Notice Letter contained no allegation of non-infringement for one or more claims of the '570 patent.

ANSWER: Admitted that the Notice Letter contained no separate allegation of non-infringement for the claims of the '570 patent but did assert that one or more claims of the '570 patent are invalid. An invalid claim cannot be infringed.

COUNT I FOR INFRINGEMENT OF THE '516 PATENT

19. Cephalon realleges and incorporates by reference paragraphs 1-18.

ANSWER: Mylan Pharmaceuticals incorporates by reference its answers to paragraphs 1-18 as if fully set forth herein.

20. Mylan has filed or caused to be filed ANDA No. 20-0043 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Mylan's generic armodafinil products before the expiration of the '516 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '516 patent is invalid, unenforceable, or not infringed.

ANSWER: Admitted with respect to Mylan Pharmaceuticals. Any other allegations, including all allegations against Mylan Inc., Matrix Ltd., and Matrix Inc., in paragraph 20 are denied.

21. By submitting its ANDA No. 20-0043 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Mylan's generic armodafinil products before the expiration of the '516 patent, Mylan has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

22. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc. have acted in concert, actively supporting, participating in, encouraging, and inducing filing of ANDA No. 20-0043 for Mylan's generic armodafinil products, and in the preparation to sell in the United States Mylan's generic armodafinil products.

ANSWER: Denied.

23. Upon information and belief, Mylan intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Mylan's generic armodafinil products with a product insert that will direct physicians and patients in the use of Mylan's generic armodafinil products.

ANSWER: Denied.

24. Upon information and belief, Mylan's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '516 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

25. Upon FDA approval of Mylan's ANDA No. 20-0043, Mylan will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Mylan's generic armodafinil products in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

ANSWER: Denied.

26. Upon information and belief, Mylan Inc. will actively aid, abet, encourage, and induce Mylan Pharmaceuticals, Matrix Ltd., Matrix Inc., and others in the production, importation, sale, offer for sale, and use of Mylan's generic armodafinil products.

ANSWER: Denied.

27. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc. will each actively participate in the production, importation, sale, offer for sale, and use of Mylan's generic armodafinil products.

ANSWER: Denied.

28. Upon information and belief, the offer to sell, sale, and/or importation of Mylan's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

29. Upon information and belief, Mylan had knowledge of the '516 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Admitted that Mylan Pharmaceuticals has knowledge of the '516 patent.

The remaining allegations in paragraph 29 are denied.

30. Upon information and belief, the offer to sell, sale, and/or importation of Mylan's generic armodafinil products would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

31. Mylan has knowledge of the '516 patent and is knowingly and willfully infringing the '516 patent.

ANSWER: Admitted that Mylan Pharmaceuticals has knowledge of the '516 patent.

The remaining allegations in paragraph 31 are denied.

32. As a result of Mylan's infringement of the '516 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

ANSWER: Denied.

COUNT II FOR INFRINGEMENT OF THE '570 PATENT

33. Cephalon realleges and incorporates by reference paragraphs 1-32.

ANSWER: Mylan Pharmaceuticals incorporates by reference its answers to paragraphs 1-32 as if fully set forth herein.

34. Mylan has filed or caused to be filed ANDA No. 20-0043 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Mylan's generic armodafinil products before the expiration of the '570 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '570 patent is invalid, unenforceable, or not infringed.

ANSWER: Admitted with respect to Mylan Pharmaceuticals. Any other allegations, including all allegations against Mylan Inc., Matrix Ltd., and Matrix Inc., in paragraph 34 are denied.

35. By submitting its ANDA No. 20-0043 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Mylan's generic armodafinil products before the expiration of the '570 patent, Mylan has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

36. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc. have acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals's filing of ANDA No. 20-0043 for Mylan's generic armodafinil products, and in the preparation to sell in the United States Mylan's generic armodafinil products.

ANSWER: Denied.

37. Upon information and belief, Mylan intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Mylan's generic armodafinil products with a product insert that will direct physicians and patients in the use of Mylan's generic armodafinil products.

ANSWER: Denied.

38. Upon information and belief, Mylan's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '570 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

39. Upon FDA approval of Mylan's ANDA No. 20-0043, Mylan will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Mylan's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

ANSWER: Denied.

40. Upon information and belief, Mylan Inc. will actively aid, abet, encourage, and induce Mylan Pharmaceuticals, Matrix Ltd., Matrix Inc., and others in the production, importation, sale, offer for sale, and use of Mylan's generic armodafinil products.

ANSWER: Denied.

41. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals, Matrix Ltd., and Matrix Inc. will each actively participate in the production, importation, sale, offer for sale, and use of Mylan's generic armodafinil products.

ANSWER: Denied.

42. Upon information and belief, the offer to sell, sale, and/or importation of Mylan's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '570 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

43. Upon information and belief, Mylan had knowledge of the '570 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '570 patent, either literally or under the doctrine of equivalents.

ANSWER: Admitted that Mylan Pharmaceuticals Inc. has knowledge of the '516 patent. The remaining allegations in paragraph 43 are denied.

44. Mylan has knowledge of the '570 patent and is knowingly and willfully infringing the '570 patent.

ANSWER: Admitted that Mylan Pharmaceuticals Inc. has knowledge of the '516 patent. The remaining allegations in paragraph 44 are denied.

45. As a result of Mylan's infringement of the '570 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

46. **ANSWER:** Denied.

PLAINTIFFS' PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. It is further denied that Cephalon is entitled to the relief requested in its Complaint or to any relief whatsoever.

AFFIRMATIVE AND OTHER DEFENSES

First Defense

The manufacture, use, sale, offer for sale, and/or importation of the product that is the subject of Mylan Pharmaceuticals' ANDA No. 20-0043 has not infringed, does not infringe, and would not infringe, either directly, contributorily or by inducement, any valid and enforceable claim of the patents-in-suit.

Second Defense

The claims of the patents-in-suit are invalid for failure to comply with one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 100 *et seq.*, including without limitation §§ 101, 102, 103, 112, 116 and/or for obviousness-type double patenting.

Third Defense

By virtue of the prior art and/or prosecution proceedings before the United States Patent and Trademark Office of the applications that led to the patents-in-suit, Cephalon is estopped from maintaining that any claim of the patents-in-suit is infringed, literally or under the doctrine of equivalents, by the product that is the subject of Mylan Pharmaceuticals' ANDA No. 20-0043.

Fourth Defense

The Complaint fails to state a claim upon which relief can be granted.

Fifth Defense

The claims of the '516 patent are unenforceable as a result of Cephalon's patent misuse, including but not limited to the improper listing of the '516 patent in the Orange Book based on Cephalon's representation in connection with NDA No. 21-875 for Nuvigil® that the '516 patent claims cover the drug for which this NDA was approved.

Sixth Defense

Mylan expressly reserves any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

For its counterclaims against Cephalon, Inc. and Cephalon France (collectively, "Cephalon"), Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") states as follows:

1. Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, with a headquarters at 781 Chestnut Ridge Road, West Virginia 26504.

2. Upon information and belief, Cephalon, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Upon information and belief, Cephalon, Inc. is in the business of manufacturing and selling pharmaceuticals products in the United States.

3. Upon information and belief, Cephalon France is a wholly-owned subsidiary of Cephalon, Inc., with a place of business at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

JURISDICTION AND VENUE

4. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the 21 U.S.C. § 355(j)(5)(C)(i).

5. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Cephalon because Cephalon has availed itself of the rights and privileges of this forum by suing Mylan Pharmaceuticals and others in this District in this case and other cases.

7. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

A. FDA Approval of Brand-Name Drugs

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Hatch-Waxman Amendments as further amended by the Medicare Prescription Drug, Improvement and Modernization Act ("Medicare Act of 2003"), sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

9. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

10. An NDA must include, *inter alia*, the number of any patent that claims the "drug" or "method of using such drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against a person not licensed by the patent

owner to engage in the manufacture, use, or sale of the drug. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

11. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Electronic Orange Book" or "Orange Book." *See* 21 U.S.C. §§ 355(j)(7)(A)(iii).

B. Generic Competition-Approval of Abbreviated New Drug Applications

12. Generic drugs are versions of brand-name drugs that typically contain the same active ingredients, but not necessarily that same inactive ingredients, as the brand-name original.

13. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the process for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

14. To receive approval of its ANDA, a generic manufacturer must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* § 355(j)(4)(F).

15. An ANDA must also contain a certification to every patent that the NDA holder has submitted to the FDA for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii), 21 C.F.R. § 314.94(a)(12).

16. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the generic manufacturer seeks FDA approval for commercial marketing of its generic drug prior to expiration of the patent to which the certification is made. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. A generic manufacturer who submits an ANDA containing a paragraph IV certification must notify both the patent owner and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

18. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file a patent infringement action against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If an infringement action is brought against the generic manufacturer, the FDA cannot approve the generic manufacturer's ANDA until the expiration of the 30-month period beginning on the date of receipt by the NDA holder/patent holder of the notice of the paragraph IV certification. *Id.*

19. If an infringement action is brought and the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the generic product described in the ANDA, the FDA will not grant approval of the ANDA earlier than the expiration date of the patent. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA. *Id.*

C. Mylan Pharmaceuticals' ANDA

20. Mylan Pharmaceuticals filed ANDA No. 20-0043 with the FDA seeking approval to market Armodafinil Tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg, ("Mylan Pharmaceuticals proposed ANDA products"), referencing Cephalon's approved NDA No. 02-1875 for Nuvigil®.

21. Cephalon listed, *inter alia*, U.S. Reissue Patent No. RE37,516 ("the '516 patent"), U.S. Patent No. 7,132,570 ("the '570 patent"), and U.S. Patent No. 7,297,346 ("the '346 patent") in the Orange Book in connection with NDA No. 02-1875 for Nuvigil®. By listing these patents, Cephalon maintains that the patents claim Nuvigil®, or a method of using the drug, and that a suit for infringement could reasonably be brought against any generic

manufacturer that attempts to seek approval to market a generic version of Nuvigil® before any of the aforementioned patents expire. *See* 21 U.S.C. § 355(b)(1)-(c)(2).

22. Because Mylan Pharmaceuticals seeks FDA approval to market Mylan Pharmaceuticals' proposed ANDA products before the expiration of each of the '516, '570, and '346 patents, Mylan Pharmaceuticals' ANDA includes a paragraph IV certification for each of these patents.

23. On or about November 2, 2009, Mylan Pharmaceuticals provided Cephalon the statutorily-mandated notice letter of its paragraph IV certification on each of the '516, '570, and '346 patents. This notice letter included a detailed statement of the factual and legal bases for its opinion that, *inter alia*, the '516, '570, and '346 patents are invalid and/or not infringed by the Mylan Pharmaceuticals' proposed ANDA products. The submission to the FDA of an ANDA containing a paragraph IV certification constitutes a technical act of infringement, which is required to give the patent holder jurisdiction to bring a patent infringement lawsuit to determine whether the listed patents are valid and infringed.

D. The '346 Patent

24. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of that Act entitled "Access to Affordable Pharmaceuticals," made certain changes to the Hatch Waxman Act. One of the changes was the inclusion of a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(C). Specifically, a generic manufacturer, like Mylan Pharmaceuticals, that has submitted an ANDA containing a paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent holder on that patent if the following have occurred: (1) 45 days have passed since the paragraph IV certification was received by the NDA holder/patent owner; (2) neither the NDA holder nor the patent holder has filed a suit for patent

infringement on the patent subject to the paragraph IV within the 45-day period; and (3) an offer of confidential access to the ANDA is included in the notice of paragraph IV certification provided to the NDA holder/patent owner. *See* 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

25. On December 11, 2009, Cephalon filed in this District a patent infringement action against Mylan Pharmaceuticals and others on two of the four Orange Book listed patents under 35 U.S.C. § 271(e). Cephalon did not allege that Mylan Pharmaceuticals' ANDA No. 20-0043 would infringe the '346 patent or that upon FDA approval of ANDA No. 20-0043, the manufacture, use, offer to sell, or sale of Mylan Pharmaceuticals' proposed ANDA products will infringe one or more claims of the '346 patent. Cephalon did not assert the fourth patent, U.S. Patent No. 4,927,855 ("the '855 patent"), because Mylan Pharmaceuticals filed a paragraph III certification for the '855 patent.

26. Since Cephalon was provided – and accepted – the offer to confidential access to Mylan Pharmaceuticals' ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III), and Cephalon did not assert the '346 patent within 45 days following receipt of Mylan Pharmaceuticals' notice letter of its paragraph IV certification, Mylan Pharmaceuticals is statutorily permitted to file and maintain a declaratory judgment action to obtain patent certainty on the '346 patent.

27. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Cephalon and Mylan Pharmaceuticals regarding infringement of the '346 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties. Mylan Pharmaceuticals is therefore entitled to bring and maintain an action for declaratory judgment for the '346 patent. *See* 21 U.S.C. § 355(j)(5)(C).

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '516 Patent)

28. Mylan Pharmaceuticals realleges and incorporates by reference the allegations of paragraphs 1-27 of its Counterclaims as if fully set forth herein.

29. The manufacture, use, sale, offer for sale, or importation of the Mylan Pharmaceuticals proposed ANDA products would not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '516 patent.

30. Mylan Pharmaceuticals is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation of the Mylan Pharmaceuticals' proposed ANDA products would not infringe, contribute to the infringement of, or induce infringement of any of the claims of the '516 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment For Delisting of the '516 Patent From the Orange Book)

31. Mylan Pharmaceuticals realleges and incorporates by reference the allegations of paragraphs 1-30 of its Counterclaims as if fully set forth herein.

32. Title XI of the MMA provides that a defendant in a suit may assert a counterclaim seeking an order requiring the holder of an NDA to correct or delete patent information submitted by the holder to the FDA for listing in the Orange Book on the ground that the patent listed does not claim an approved drug or an approved method of using the drug. *See* 21 U.S.C. § 355(j)(5)(C)(ii).

33. The '516 patent does not claim in connection with NDA No. 21-875 for Nuvigil® the drug for which the NDA was approved, and therefore, the '516 patent must be delisted.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '570 Patent)

34. Mylan Pharmaceuticals realleges and incorporates by reference the allegations of paragraphs 1-33 of its Counterclaims as if fully set forth herein.

35. The claims of the '570 patent are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 100 *et seq.*, including without limitation §§ 102, 103, 112, 116 and/or for obviousness-type double patenting.

36. Mylan Pharmaceuticals is entitled to a declaratory judgment that the claims of the '570 patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '346 Patent)

37. Mylan Pharmaceuticals realleges and incorporates by reference the allegations of paragraphs 1-36 of its Counterclaims as if fully set forth herein.

38. There is a substantial and continuing controversy between Cephalon and Mylan Pharmaceuticals regarding infringement of the '346 patent.

39. The manufacture, use, sale, offer for sale, or importation of the Mylan Pharmaceuticals' proposed ANDA products would not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '346 patent.

40. Mylan Pharmaceuticals is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation of the Mylan Pharmaceuticals' proposed ANDA products would not infringe, contribute to the infringement of, or induce infringement of any of the claims of the '346 patent.

PRAYER FOR RELIEF

WHEREFORE, Mylan Pharmaceuticals respectfully requests that this Court enter a judgment and decree in its favor and against Cephalon:

a) Dismissing the Complaint herein in its entirety with prejudice;

b) Declaring that no valid claim of each of the '516 patent and the '346 patent is infringed;

c) Declaring that '516 patent does not contain claims to the Nuvigil® drug for which the application was approved as listed in the Orange Book and accordingly order that Cephalon delist or otherwise delete the '516 patent in connection with NDA No. 21-875 for Nuvigil®;

d) Declaring that each of the claims of the '570 patent asserted by Cephalon against Mylan Pharmaceuticals' proposed ANDA products is invalid;

e) Permanently enjoining Cephalon, its officers, agents, directors, servants, employees, subsidiaries, and assigns, and all those acting under the authority of or in privy with them or with any of them, from asserting or otherwise seeking to enforce each of the '516 patent, the '570 patent, and the '346 patent against Mylan Pharmaceuticals' proposed ANDA products;

f) Declaring that this case is an exceptional case under 35 U.S.C. § 285 and awarding Mylan Pharmaceuticals its attorneys' fees, costs, and expenses; and

g) Awarding Mylan Pharmaceuticals any further additional relief as the Court deems just and proper.

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Dated: February 12, 2010

CERTIFICATE OF SERVICE

I, James L. Higgins, hereby certify that on February 12, 2010, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on February 12, 2010, I caused a copy of the foregoing document to be served by e-mail on the above-listed counsel and on the following:

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